

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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**THE PROCTER & GAMBLE COMPANY,**

**Plaintiff,**

**v.**

**ULTREO, INC.,**

**Defendant.**  
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**Civil Action No. 07-8379 (RJS)**

**DIRECT EXAMINATION  
DECLARATION OF JOEL BERG**

I, JOEL BERG, hereby declare under penalty of perjury as follows:

**Background And Qualifications.**

1. I am Professor and Chairman of the Department of Pediatric Dentistry at the University of Washington ("UW") School of Dentistry. I am a Board Certified Pediatric Dentist and am a Trustee of the American Academy of Pediatric Dentistry. I am also one of the founders of Ultreo, Inc. ("Ultreo") the company. A copy of my CV is annexed hereto as Exhibit A and can also be found at DX-63.<sup>1</sup>

2. Prior to joining the faculty of UW, from 2000 to 2003, I was Vice President of Clinical Affairs at Philips Oral Healthcare ("Philips"), the maker of the Sonicare power toothbrush. In that position, I directed all of the clinical and laboratory research conducted or sponsored by Philips relating to its Sonicare power toothbrush.

3. From 1998 to 2000, I was head of the Scientific Department for EPSE Dental AG, now a subsidiary of the 3M Corporation, which sells dental products to dental professionals worldwide. I supervised clinical and laboratory research at that company as well. Prior to that, I

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<sup>1</sup> Ultreo's hearing exhibits are referred to herein as "DX-\_\_."

served as the Director of the Postgraduate Residency Program in Pediatric Dentistry at the University of Texas, Houston, where I supervised clinical and laboratory research in pediatric dentistry.

4. I have conducted numerous clinical trials and laboratory studies in the field of oral health care. I have written extensively on topics relating to *in vivo* and *in vitro* research in the field of oral health and am the author of more than 85 manuscripts, abstracts and book chapters relating to a variety of subjects pertaining to dentistry and oral biology. I have also spoken at numerous seminars on the topic of dental research.

5. I hold a B.A. degree from Yeshiva University, a D.D.S. from the University of Iowa, and an M.S. degree in Oral Biology from the University of Iowa.

6. I have been engaged as an expert in this matter by Ultreo. For my services, I am being compensated at the rate of \$350 per hour, except for time during deposition or court appearances for which I am being compensated at the rate of \$500 per hour.

7. Between 2003 and 2006, I have testified as an expert witness in three cases on behalf of the State of Washington Department of Health concerning Medicaid malpractice claims brought by the State of Washington.

**P&G's Contentions In This Case.**

8. At the outset, it is important to be precise about what P&G is claiming. P&G does not — and, indeed, cannot — claim that Ultreo has no clinical studies supporting the efficacy of its toothbrush with respect to plaque removal or gingivitis. Ultreo has sponsored several clinical studies that are published on its website demonstrating the efficacy and safety of its product. Those studies, with which I am familiar, are described in the Direct Examination Declaration of Dr. James Christopher McInnes, Ultreo's Principal Scientist ("McInnes Direct Exam Dec.") at ¶¶ 9-12.

9. In my judgment, Ultreo's sponsored clinical research, as described above, is conducted in accordance with industry and academic standards. Proper controls were maintained in these studies and all potential biases were guarded against. In my opinion, those studies are reliable and validly support Ultreo's claims regarding the safety and efficacy of its power toothbrush.

10. P&G's position in this case is that Ultreo's clinical studies are not sufficient because they do not isolate and test the plaque removal capabilities of the ultrasound technology incorporated in the Ultreo toothbrush. That is, even though Ultreo's clinical research establishes that the combined effects of the sonic bristle action with ultrasound waves of the Ultreo toothbrush removed clinically relevant quantities of plaque, P&G asserts that Ultreo must also conduct and publish clinical studies that establish the plaque removal capabilities of the ultrasound component alone.

11. There is no industry requirement of which I am aware that mandates that each component of what collectively constitutes a power toothbrush be tested separately in a clinical setting. Indeed, as I explain later in this declaration, P&G itself has not published clinical studies that isolate and test the plaque removal capabilities of the combined technologies it employs in the premium power toothbrushes and other oral care products that it currently markets to public consumers.

12. Nor is there an industry requirement that mandates that a power toothbrush's efficacy must be tested in a clinical setting, as opposed to a laboratory setting. To the contrary, as I explain below, Philips, a market leader in power toothbrushes, relies on laboratory studies to support its longstanding claims concerning the ability of the Sonicare power toothbrush to clean plaque beyond the reach of its bristles. Moreover, as Mr. Gallagher points out in his Direct Examination Declaration, P&G currently makes advertising claims regarding the bacteria-reducing potential of several products, including oral care products, based solely on laboratory studies and makes those

claims directly to consumers. Gallagher Direct Exam at ¶¶ 52-53.

**The Accepted Validity Of Philips' Laboratory Tests.**

13. Dr. Biesbrock candidly acknowledges that Ultreo is not the only power toothbrush company that conducts laboratory studies and makes advertising claims based in whole or in part on those studies. In paragraph 12 and footnote 1 of his Affidavit, Dr. Biesbrock lists many of the published laboratory studies conducted or sponsored by Philips and its predecessors regarding the Sonicare power toothbrush.

14. Dr. Biesbrock's list of Philips' laboratory studies is not complete. He neglects to mention that Philips has recently released a Compendium of recent studies: *Review of Key Clinical Research on the New Philips Sonicare FlexCare: A Compendium of Continuing Education in Dentistry* 2007; 28. The Compendium, a copy of which can be found at DX-54, reports on at least three new laboratory studies conducted or sponsored by Philips. One study relates to Philips' claim that the Sonicare toothbrush has the ability to clean and to remove plaque bacteria beyond the reach of its bristles. (DX-54 at 10). A second study reports on the Sonicare's ability to deliver fluoride in areas between teeth where plaque bacteria is not removed by either direct bristle action or hydrodynamic shear forces. (DX-54 at 15). The third test article reports on a series of laboratory studies showing that the Sonicare is not abrasive to restorative materials or orthodontic brackets and is more gentle on dentin than the Oral-B Triumph power toothbrush. (DX-54 at 42). Thus, to this day, Philips continues to conduct laboratory studies and to make claims regarding its product on the basis of those studies.

15. According to Philips, the Sonicare toothbrush combines the elements of direct mechanical brushing with fluid dynamic forces generated by increased bristle velocity and frequency. Philips claims that the Sonicare's combined use of these technologies enables its

product to remove plaque bacteria in the interproximal areas of the mouth in which the bristles do not penetrate. I will refer to this simply as a "beyond-the-bristles" claim.

16. Philips makes a beyond-the-bristles claim not only to dental professionals, who are sufficiently knowledgeable to be able to independently evaluate the merits of Philips' supporting research, but also directly to consumers. Thus, for example, on its website, Philips has claimed that Sonicare toothbrushes create "tiny, but powerful waves" that are able to "dislodg[e] plaque that isn't normally reachable by a manual brush, nor the oscillating or rotating movement of the power brushes."<sup>2</sup> The website further claims, "In fact, Dynamic Fluid Cleaning Action can actually make it easier to clean plaque below the gumline." *See also* Biesbrock Deposition, DX-144 at 37

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17. Significantly, Philips has conducted or sponsored numerous clinical studies that evaluate the plaque removal capabilities of its product, but only as a complete integrated product (*i.e.*, a product that utilizes *both* mechanical brushing action and dynamic fluid activity). It has never published any clinical study that purports to isolate the benefits of the dynamic fluid forces. Instead, the *sole* basis upon which Philips relies to make beyond-the-bristles claims or extol the cleaning benefits of the dynamic fluid action are laboratory studies, including a laboratory study that formed the basis of one of the laboratory studies upon which Ultreo relies to show that the Ultreo toothbrush has the ability to remove plaque bacteria beyond the reach of the bristles. *See* Biesbrock Deposition of November 28, 2007, DX-144 at 38

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<sup>2</sup> The latter is clearly a reference to the Oral-B power brush. A copy of a Philips' website page describing its "Sonic technology," as well as copies of other Philips' advertising claims in this regard, can be found at DX-55 – DX-60.

18. The reason for Sonicare's reliance on laboratory studies is understandable. While traditional clinical studies involving the assessment of the plaque removal capabilities of toothbrushes by visible detection in human subjects and scoring by dental examiners are a valuable research tool, they have significant limitations.

19. Power toothbrushes on the market today tend to score extremely well in these traditional clinical studies that were originally designed to measure the performance of manual toothbrushes and other oral healthcare products. Direct mechanical brushing removes so much of the visible plaque on teeth that is hard to ascertain through visual examination of teeth whether there are any additional benefits from other technologies utilized in modern power toothbrushes, particularly where these technologies are designed to address plaque accumulation in hard to reach or hard to see areas.

20. Consequently, Philips has conducted traditional visible plaque removal studies to test the generally efficacy of its brush, but has not relied upon such studies to support its beyond-the-bristles claims. For that, Philips has utilized sophisticated laboratory studies that are designed to isolate and test the effects of the dynamic fluid actions generated by its product. These studies are published in peer-reviewed professional dental journals and are respected by many dental professionals and industry participants.

21. It is important to note that Philips is not just one power toothbrush company making claims in the market based on laboratory studies. According to P&G's own witness, Wayne Randall, Philips controls 62% of the retail premium power toothbrush market, with P&G controlling the remaining 38%. (Randall Aff. at ¶ 6). Philips is, therefore, the market leader in this category. It sets the standards for the industry and those standards include the use of laboratory studies to support technology claims.

22. P&G is essentially insisting that Ultreo be held to a higher standard than that utilized by the market leader. Indeed, with 62% of the market, it is fair to say that a significant majority of the premium power toothbrushes that are being sold in this country today are being sold by Philips on the basis of advertising claims using laboratory studies. It is inconceivable that Philips would be this successful in selling its product if its laboratory studies were viewed by the market as unreliable, or if the dynamic fluid benefits that Philips claims were deemed to be "unproven."

23. Significantly, the Sonicare is not only extremely popular with the consumer, it is widely accepted in the dental professional market. These extremely knowledgeable professionals have recommended the Sonicare to their patients and are then able to assess the efficacy of the product by examining and treating their patients over time. Sonicare's popularity and success in the dental professional market is further evidence that its research and advertising claims are accepted as valid and truthful. It is ludicrous to suggest that these sophisticated professionals would permit their patients to purchase (at a significant cost) and use a product the benefits of which are wholly speculative and not supported by any valid science, as P&G seems to suggest here.

24. Indeed, P&G itself has publicly embraced the truth and accuracy of Sonicare's beyond-the-bristles claims based on laboratory tests. In 2004, P&G and Philips jointly developed and marketed a product which combined a Sonicare power toothbrush with an integrated Crest brand toothpaste dispenser. The product was called the "IntelliClean System." At the time the product was launched in 2004, P&G and Philips jointly published and disseminated to the dental community a "Compendium" of clinical and laboratory research regarding the IntelliClean System.<sup>3</sup> The Compendium prominently discloses on its cover that the research reflected therein was "Supported by . . . The Procter & Gamble Company." See Biesbrock Dep., DX-144 at 76-77

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<sup>3</sup> A copy of the IntelliClean System Compendium, produced by P&G in this action, can be found at DX-37.

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25. The Compendium includes a laboratory study sponsored by P&G and Philips confirming the beyond the bristles cleaning capabilities of the IntelliClean System. In the introduction to the research, Ashley P. Barlow, a P&G Senior Scientist, and Douglas Dudgeon, Scientific Affairs Manager of Philips, state that the IntelliClean System "has also been shown in vitro by Yuen and coworkers to exhibit beyond the bristles cleaning and to be gentle on dentin, significantly more so than the Oral B ProfessionalCare 7000, a leading rotational oscillation toothbrush."<sup>4</sup> They also state: "According to in vitro studies . . . such fluid activity [of the Sonicare brush] can remove plaque from beyond the reach of the bristles significantly better than a rotational-oscillation power toothbrush."<sup>5</sup> As Dr. Biesbrock has testified, P&G **REDACTED** those studies – studies that are unmistakably at odds with the contentions that P&G now sees fit to make in this litigation. (Biesbrock Dep., DX-144 at 89).

26. I have reviewed the expert report of Dr. Genco and nowhere does he opine that in vitro plaque biofilm testing is scientifically invalid. Indeed, I note that while Dr. Genco was Editor in Chief of the Journal of Periodontology, an article was approved for publication entitled "In vitro assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by two electric toothbrushes" written by Drs. Hope, Petrie and Wilson. *J. Periodontol* 2003;74:1017-22. (DX-40). In that article, Dr. Hope and his co-authors posit that in vitro lab studies are actually more reliable than traditional clinical plaque removal studies. Dr. Genco's position, as stated in his deposition, is

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<sup>4</sup> Intelliclean Compendium, DX-37 at 7.

<sup>5</sup> Intelliclean Compendium, DX-37 at 5.



(Genco Deposition, DX-154 at 110-15).

**Dr. Biesbrock Overstates The Importance Of Clinical Research.**

27. Dr. Biesbrock further contends that Philips' laboratory studies are in "diametric contrast" to clinical studies conducted by P&G. I totally disagree. The clinical studies to which Dr. Biesbrock makes reference are standard plaque removal studies comparing an Oral-B toothbrush with a Sonicare model. Even if the results of these studies are given full credence (which I do not believe appropriate for reasons I discuss later), the fact that the Oral-B purportedly scored higher in some plaque removal tests does not mean that the Sonicare does not clean beyond-the-bristles. It may simply mean that in these particular subjects the mechanical action of the Oral-B power toothbrush was more successful in removing visible plaque than the combined technologies of the Sonicare model. The results of these Oral-B studies do not disprove the findings of Philips' laboratory tests.

28. The phrase "diametric contrast" is, however, appropriate to use when describing the relationship between P&G's clinical studies and Philips' *clinical* studies. Philips has conducted several clinical studies that purportedly show that the Sonicare toothbrush is superior to the Oral-B power toothbrush with respect to visible plaque removal. The results of these studies, if valid, are irreconcilably inconsistent with the results of P&G's clinical studies that purport to show the opposite. Clearly, P&G and Philips cannot each credibly claim that its respective power toothbrushes consistently and without exception outperform the other in the clinical context. And yet that is precisely what is occurring today. P&G's website discloses nine different clinical studies where an Oral-B power toothbrush supposedly outperforms a Sonicare with respect to plaque or stain removal or gingivitis reduction, while Philips' website discloses three clinical studies showing that the Sonicare is superior to the Oral-B power toothbrush.

29. This blatant inconsistency undermines P&G's claims regarding the supposed unimpeachable value of clinical research. Many respected professionals in the oral health field today have become increasingly skeptical when it comes to clinical research. Large companies such as P&G and Philips are perceived as fixing the results of clinical research by jerry-rigging the selection of subjects, providing incomplete brushing instructions, manipulating the test data, or massaging the statistical analysis so as to achieve a desired result.

30. It is noteworthy in this regard that P&G's website discloses 24 different clinical studies comparing an Oral-B power toothbrush with a competing power toothbrush. The studies compare the products with respect to their abilities to remove plaque, reduce gingivitis or eliminate stains. Except for one instance where there was no significant difference between the brushes, in each test the Oral-B power toothbrush proved to be superior to the competing power toothbrush, regardless of the model, manufacturer or the parameter being measured. P&G's website discloses an additional 17 clinical studies comparing an Oral-B power toothbrush to a manual toothbrush. In each of those studies, the Oral-B power toothbrush purportedly proved superior. In sum, P&G would have us believe that their record is an astonishing 40-0-1 in clinical comparative toothbrush testing.<sup>6</sup>

31. If one looks to the Philips' website, a similar result is gleaned as to the performance of its product. Philips discloses seven clinical studies comparing the Sonicare with a competing power toothbrush and in each test the Sonicare outperforms the other brush. It discloses another six clinical studies where the Sonicare outperformed manual toothbrushes. According to Philips' website, Sonicare is an undefeated 13-0 versus the competition.<sup>7</sup>

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<sup>6</sup> A summary of those 41 studies conducted or sponsored by Oral-B can be found at DX-61.

<sup>7</sup> A summary of those 13 studies conducted or sponsored by Philips can be found at DX-62.

32. It is circumstances such as these that have prompted many in the oral healthcare field to discount the importance and value of clinical research, which is largely funded and controlled by the sponsoring manufacturer. It is far from independent research, nor is it reviewed and approved by independent regulatory bodies. Consequently, P&G is wrong to suggest that the industry views clinical studies as unquestionably valid and reliable.

**Dr. Biesbrock's Criticisms Of The Philips' Testing Procedure Are Meritless.**

33. Dr. Biesbrock and Dr. Genco claim that *in vitro* studies are unreliable because the plaque bacteria used in laboratory studies does not mimic the various types of bacteria that are found in the human mouth. This criticism is wrong and highly misleading. *S. Mutans* has always been of particular interest to dental researchers because it is a particularly sticky form of plaque bacteria and thus, is well-suited to determine the plaque removal capabilities of a toothbrush. Also, it is a bacteria that is known to be harmful to teeth, as it has been determined to be a cause of cavities.<sup>8</sup> Thus, for years the scientific community has used *S. Mutans* as a valid representative of the plaque bacteria that is in a person's mouth.<sup>9</sup>

34. Furthermore, Philips has replicated its *S. Mutans* laboratory tests using multi-species plaque bacteria biofilms that it harvested from both human saliva and artificial saliva samples.<sup>10</sup>

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<sup>8</sup> Van Houte J., Role of micro-organisms in caries etiology. *J. Dent. Res.* 1994; 73:672-91 (DX-64).

<sup>9</sup> Wu-Yuan, C., McInnes, C., Ability of the Sonicare electronic toothbrush to generate dynamic fluid activity that removes bacteria, *J. Clin. Dent.* 1994;5:89-93 (DX-43); Adams, H., Winston W.T., Heersink J., et al., Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing, *Am J. Dent.* 2002;15 (spec. no.):12B-17B [published correction appears in *Am. J. Dent.* 2002;15-46] (DX-38).

<sup>10</sup> Aspiras, M., et al., In vitro evaluation of interproximal biofilm removal with power toothbrushes, *Review of Key Clinical Research on the New Philips Sonicare FlexCare: A Compendium of Continuing Education in Dentistry* 2007; 28: 10-14 (DX-36); Hope, C.K., Wilson, M., Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using in vitro oral biofilms, *Am J. Dent.* 2002; 15 (spec. no.): 7B-11B (DX-41); Hope, C.K., Petrie, A.,

Using these multi-species plaque biofilms, instead of *S. Mutans*, in its laboratory tests has not changed the results Philips obtained. Thus, there is strong evidence that any differences between *S. Mutans* and the supposedly more complex compositions of plaque bacteria that would appear in the human mouth do not affect the validity of Philips' laboratory tests.

35. Dr. Biesbrock further claims that *in vitro* studies are not accurate predictors of "in the mouth" performance because "the presence of salivary protein in the mouth may impact the effectiveness of plaque removal efforts." This criticism, too, fails. First, Philips (as well as Ultreo) coats the testing substances with gastric mucin, a substance that has been commonly used as a substitute for human saliva.<sup>11</sup> Thus, the salivary protein factor does exist in the brushing environment in Philips' laboratory test. Second, Philips has also replicated its laboratory brushing exercise in mouths of human volunteers, which would introduce the salivary component into the brushing. Utilizing that procedure, Philips obtained results that were comparable to the results it obtained in its laboratory studies.<sup>12</sup> Thus, the absence of saliva does not affect the validity of Philips' laboratory test.

36. Dr. Biesbrock also contends that supposed differences exist between the level of the fluid environment in the laboratory study and the amount of saliva found in the mouth. These assertions do not hold water. Dr. Biesbrock is wrong in contending that only 1.07 milliliters ( $\pm$  .39ml) will typically exist in the human mouth during toothbrushing. The article Dr. Biesbrock

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Wilson, M., In vitro assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes, *J. Periodontol.* 2003;74:1017-22 (DX-40).

<sup>11</sup> Hope, C.K., Wilson, M., Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using in vitro oral biofilms, *Am J. Dent.* 2002; 15 (spec. no.): 7B-11B (DX-41); Hope, C.K., Petrie, A., Wilson, M., In vitro assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes, *J. Periodontol.* 2003;74:1017-22 (DX-40).

<sup>12</sup> Stanford, C.M., et al., Removal of supragingival plaque in an intraoral model by use of the sonicare toothbrush, *J. Int. Acad. Periodontol.*, 2000 Oct; 2(4):115-9 (DX-65).

cites references quantities of saliva typically present in the resting state — *i.e.*, when the person is not eating or engaging in some other activity that generates additional saliva such as toothbrushing. Nor does it take into account the additional fluid present in the mouth when the user wets the brush prior to brushing in accordance with the manufacturer's instructions.

37. Dr. Biesbrock is also incorrect in stating that the toothbrush head is fully submerged in Philips' or Ultreo's laboratory test. In fact, in both tests only portions of the bristles are inserted into the liquid medium because the optimal performance of both products requires air to produce the bubbles required for beyond-the-bristles cleaning effects.

38. The remaining criticisms of Dr. Biesbrock and Dr. Genco can be swiftly dispatched. While not all surfaces used in laboratory studies resemble teeth, the hydroxyapatite disks used in the Sonicare study and in Ultreo's laboratory study have been well-accepted as a substitute for enamel in the growth of in vitro plaque bacteria.<sup>13</sup> Hydroxyapatite discs contain the mineral found in human enamel. Finally, Dr. Biesbrock's assertion about laboratory tests not using toothpaste is inapplicable. The Ultreo laboratory tests, like the Philips' test, use toothpaste.<sup>14</sup>

39. Dr. Biesbrock's conclusion at page 18 that laboratory studies, while valuable, "are only the initial step in a comprehensive analysis of an issue before confirming the conclusion clinically," is erroneous. *Philips has never confirmed clinically the findings of its laboratory studies that the Sonicare cleans beyond-the-bristles.* Indeed, the study that Dr. Biesbrock cites to support his statement is not an industry treatise. It is an Oral-B study written at the direction of Paul Warren, a long-time clinical research director with Oral-B. The industry standard is what is actually practiced by the market leaders, not what Paul Warren thinks it should be.

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<sup>13</sup> See nn. 9 & 10 *supra*.

<sup>14</sup> See McInnes Direct Exam Dec. at ¶ 46.

40. Ultreo's laboratory test addressing the plaque removal capabilities of its ultrasound technology are described in the declaration of Dr. McInnes. As the former Principal Scientist at Optiva, the creator of the Sonicare brush and the predecessor of Philips, Dr. McInnes is well-experienced in conducting this test, which is modeled on the publicly available laboratory test that Philips has been conducting and using for years. In my opinion, the study was validly conducted and proves the plaque-removal capabilities of the ultrasound component of the Ultreo brush. Thus, to the extent that potential users are interested in determining whether both the sonic and ultrasonic components of the toothbrush can separately remove significant quantities of plaque, Ultreo's laboratory research also establishes that the ultrasound emissions, by themselves, can remove relevant quantities of plaque.

**P&G's Clinical Study Is Flawed.**

41. Regarding P&G's clinical study with respect to the Ultreo, I have reviewed the Direct Examination Declaration of Dr. McInnes and I wholeheartedly agree with his criticisms of that study. The study is flawed because it failed to isolate and test the ultrasound technology of the Ultreo and because the procedure in which the brushhead was held three millimeters from the teeth in a subject's open mouth could not produce the fluid coupling required for the Ultreo's ultrasound to be effective. It is an absurd experiment and reflects poorly on P&G's research methodologies.

42. Further, it has become clear as a result of the discovery process in this case that P&G's study was conducted on subjects, all of whom were P&G employees. Significantly, this fact was not disclosed in the protocol, the article submitted by Dr. Biesbrock for publication or Dr. Biesbrock's affidavit to this Court. Indeed, Dr. Genco has admitted that

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(Genco Dep., DX-154 at 191). The undisclosed use of a company's employees as the sole subjects in a brushing study involving a competitor's brush, where the

employees are not blinded to the treatment, is highly improper and, by itself, makes the study and its results completely unreliable.

43. It is interesting that while Dr. Biesbrock emphasizes the differences between laboratory studies and "real world conditions," he completely ignores the ways in which clinical plaque removal studies differ from real world conditions. P&G directed the subjects to refrain from all oral hygiene procedures for a full day prior to the treatments. It instructed them to refrain from eating, drinking, chewing gum and smoking for four hours prior to treatments. Subjects were asked to swish their mouths with red dye prior to the examinations. They were asked to switch toothpastes on the second day prior to the treatment. None of these procedures correlates to real world conditions.

44. The P&G study is also flawed because the conclusion that the Ultreo performs better when used as a manual toothbrush is inconsistent with the scientific literature showing that power toothbrushes are superior to manual toothbrushes. Contrary to Dr. Biesbrock's contention, the recognized superiority of power toothbrushes is not limited to Oral-B brushes. As Oral-B's own study by Paul Warren states: "Both types of powered toothbrushes used in our study, the Oral-B oscillating/rotating brush and the high frequency Sonicare brush, have shown advantages over manual brushing in the removal of plaque, mostly notably from interproximal regions."<sup>15</sup> Indeed, in another article, Dr. Warren flatly stated that "a large number of well-designed short- and long-term controlled clinical studies . . . consistently have shown the power toothbrush to be superior, with results demonstrating greater plaque removal and, as a consequence, more improvement in gingival condition than that achieved with a manual toothbrush alone."<sup>16</sup>

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<sup>15</sup> Biesbrock Affidavit, DX-73, Exhibit J.

<sup>16</sup> Warren, P, et al., A practice-based study of a power toothbrush: assessment of effectiveness and acceptance, *J. Am. Dent. Assoc. (JADA)* 2000;131:389-94 at 389 (DX-66).



45. Significantly, Ultreo makes claims regarding the plaque removal capabilities of its ultrasound technology to dental professionals, not consumers. Further, Ultreo tells dental professionals that these claims are based on laboratory studies. Ultreo publishes abstracts of all of its clinical and laboratory studies on its website. Dental professionals can determine for themselves whether a laboratory test is sufficiently similar to a clinical situation that it can be relied upon. Dentists and other dental professionals are a sophisticated and knowledgeable group. They are able to exercise their own judgment and determine for themselves if Ultreo's science supports its advertising statements. They clearly know the difference between a clinical and a laboratory study.

46. Some dental professionals prefer laboratory research since it is better suited to control the different variables involved in oral health research. Others prefer clinical research. To the extent the issue is important to them, they can make up their own minds as to whether Ultreo's *in vitro* research is a reliable predictor of what will occur in their patients' mouths.

47. Finally, P&G's contention that clinical studies are necessary to support claims regarding the separate plaque-removal effects of combined technologies is belied by its own practice in this regard. A review of its website indicates that P&G does not have clinical studies supporting the claimed capabilities of discreet technologies when it combines them into an integrated product.

48. For example, P&G claims on its website that its high-end products, the Oral-B Triumph and the Oral-B Professional Care 8000 Series, are the "only" power toothbrushes that combine two mechanical technologies: A rotating or oscillating movement of its brushhead and an in-and-out pulsating movement.<sup>17</sup> Yet, the website discloses no clinical study that I could find that shows that the pulsating feature actually enhances the plaque removal capabilities of these products.

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<sup>17</sup> See Biesbrock Dep., DX-144 at 41 ;  
<http://www.oralb.com/us/products/product.asp?tid=products&sub=power&cid=power&pid=pc8000>  
 (DX-69); <http://www.oralb.com/us/products/power/triumphsmartguide/> (DX-149-51).



49. The only study I was able to find on the Oral-B website involving the separate plaque removal capabilities of the pulsating technology involved a testing of a 1998 model brush that to my knowledge is no longer commercially available.<sup>18</sup> There is no valid reason to assume that even if the pulsating feature was a significant enhancement to a 1998 model's plaque removal capabilities, it remains a significant enhancement in a 2007 model. Indeed, as Dr. Biesbrock conceded in his deposition,

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50. Notably, during the course of his deposition, Dr. Biesbrock stated that

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51. Another example where P&G does not have a clinical study addressing components of combined technologies involves the Oral-B ProfessionalCare Oxyjet Center, which is a kit consisting of two products: an Oxyjet oral irrigator and an Oral-B power toothbrush. Oral-B's

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<sup>18</sup> Ernst, C., Clinical plaque removing efficacy of a new power toothbrush, *Am. J. Dent.*, 1998; 11 (Spec. No):S13-6 (DX-78). See also Biesbrock Dep. at 41-47 (DX-144).

website claims that the irrigator is the "world's first oral irrigator with unique micro-bubble technology." Supposedly, "it mixes air and water, then pressurizes it to form millions of long-lasting micro-bubbles designed to attack plaque bacteria."<sup>19</sup>

52. P&G has not disclosed that it has conducted any clinical study that purports to isolate the "microbubble technology" from the fluid streaming forces of the irrigator. The only study disclosed is one involving the use of the irrigator with an unspecified manual toothbrush.<sup>20</sup> This study was not even designed to test whether the "microbubble technology" of the Oxyjet provided any plaque removal effect independent of the fluid streaming action. Moreover, that study did not even find a statistically significant plaque removal to using the oral irrigator at all.

53. Indeed, I have reviewed documents produced by P&G in this action that demonstrate that the only study that could possibly support a P&G claim that the Oxyjet's microbubbles purportedly attack plaque bacteria is a *laboratory* study. DX-84 is a slide presentation produced by P&G. That slide presentation contains a chart that demonstrates that

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<sup>19</sup> <http://www.oralb.com/us/products/product.asp?tid=products&sub=power&cid=power&pid=oxyjet> (DX-70).

<sup>20</sup> Frascella, J.A., et al., A randomized clinical evaluation of the safety and efficacy of a novel oral irrigator, *Am. J. Dent.* 2000;13:55-58 (DX-68).

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54. The above two examples plainly show that P&G itself does not have clinical studies to support the claimed synergistic benefits of multiple technologies in products. It boldly proclaims that Ultreo must isolate and test the plaque removal capabilities of the ultrasound technology incorporated in the Ultreo toothbrush, while, as Dr. Biesbrock candidly acknowledged during the course of his deposition, it

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November 9, 2007  
Stipulated Confidentiality Order In This  
Action

55. In sum, P&G itself does not even meet the standard that it seeks to impose on Ultreo in this case. This plainly reveals that P&G isn't really concerned about advertising in this case. P&G's ultimate goal is to protect its market share and preclude completion from Ultreo's innovative product.

Date: December 11, 2007  
Seattle, Washington.

  
Joel Berg

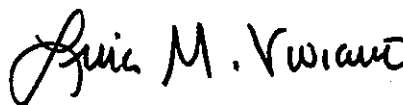
**CERTIFICATE OF SERVICE**

I hereby certify under penalty of perjury that on December 12, 2007, I caused a copy of the foregoing **REDACTED DIRECT EXAMINATION DECLARATION OF JOEL BERG** to be served upon counsel for The Procter & Gamble Company by the Court's ECF Filing System and by hand delivery to the following individual:

Laura W. Sawyer  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, New York 10017

**Attorneys for The Procter & Gamble Company**

Dated: New York, New York  
December 12, 2007

A handwritten signature in black ink, appearing to read "Lina M. Viviano", written in a cursive style.

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Lina M. Viviano